K082616

510(k) SUMMARY

[as required by section 807.92(c)]

SEP 2 6 2008

General Information

Submitted by:	Haselmeier GmbH Dufourstr. 32 CH-8008 Zurich Switzerland
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Date Prepared:	September 4, 2008

Device Name

Trade Name:	Haselmeier Pen 8
Common Name:	Piston syringe

Predicate Devices

Haselmeier Pen	K070100	Haselmeier Sàrl

Device Description

The Haselmeier Pen 8 is a reusable pen-injector designed to provide a method of accurately subcutaneously injecting the desired dose of medication from single lumen hypodermic needle. The device can be used by health professionals or for self-injection by the patient.

The pen-injector uses 3.0-mL cartridges of medication and a single use, detachable and disposable needle (supplied separately). The pen injector allows the user to dial the desired dose (0.08 mL).

The device is compatible with commercially available pen needles (supplied separately) that comply with: ISO 11608-2:2000 Pen-injectors for medical use - Part

2: Needles - Requirements and test method and 3-mL ISO type A cartridges (supplied separately), which meet ISO 11608-3: 2000 Pen-injectors for medical use _ Part 3: Finished cartridges - Requirements and test methods, with the following dimensions:

Overall cartridge length including aluminum cap: 63.9 mm+/- 0.3 mm
Outside Cartridge Diameter: 11.94 mm MAX.
Inner Cartridge Diameter: 9.65 mm +/- 0.1 mm measured at open end.
Maximum eccentricity of aluminum cap: 0.33 mm

Intended Use
The Haselmeier Pen 8 is a hand-held mechanical device intended for subcutaneous self administration of FDA-approved drugs and biologics. The Haselmeier Pen 8 is designed to be used with 3.0 mL cartridges which are prefilled prior to injection. The Haselmeier Pen 8 is for use in the home environment to aid and support prescribed treatment and therapy.

Technological Comparison
The Haselmeier Pen 8 has similar indications for use and overall function and performs in a similar manner with respect to the Haselmeier Pen 60.
The technological characteristics of the Haselmeier Pen 8 and its drug cartridge are the same as product currently legally marketed in the USA.

Performance Data
The Haselmeier Pen 8 has been demonstrated to perform as intended.
The Haselmeier Pen 8 conforms to the requirements when tested using the methods specified in the ISO Standard, ISO 11 608- 1:2000, "Pen-injectors for Medical Use _
Part 1 Requirements and Test Methods."

Conclusion
Haselmeier concludes based on the information presented that the Haselmeier Pen 8 is substantially equivalent to products currently, legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

Haselmeier GmbH
C/O Mr. Stephen J. Goldner
President
Regulatory Affairs Associates, Incorporated
30833 Northwestern Highway, Suite 121
Farmington, Michigan 48334-2581

Re: K082616
Trade/Device Name: Haselmeier Pen 8
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: September 5, 2008
Received: September 9, 2008

Dear Mr. Goldner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Haselmeier Pen 8

Sponsor Name: Haselmeier GmbH

Indications for Use:

The Haselmeier Pen 8 is a hand-held mechanical device intended for subcutaneous self-administration of FDA-approved drugs and biologics. The Haselmeier Pen 8 is designed to be used with 3.0 mL cartridges which are prefilled prior to injection. The Haselmeier Pen 8 is for use in the home environment to aid and support prescribed treatment and therapy.

Prescription Use ☒ (21 CFR 801 Subpart D) Or Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

·Division Sign-Off)
)ivision of Anesthesiology, General Hospital
·nfection Control, Dental Devices

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